Criteria of person eligible as a donor, evaluation terms and procedure and a list of diseases and other factors excluding or limiting blood donation

Passed 29.04.2005 No. 65
RTL 2005, 50, 707
Entry into force 15.05.2005

Amended by the following acts

Passed | Published | Entry into force
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23.02.2011 | RT I, 07.03.2011, 1 | 10.03.2011

The Regulation is established under subsection 7 (5) of the Blood Act.

Chapter 1
GENERAL TERMS

§ 1. Scope of application

The Regulation establishes criteria for the evaluation of eligibility of a person as a donor (hereinafter donor selection), including a list of diseases or other factors excluding or limiting blood donation and the terms and procedure for donor selection, considering voluntary free blood donation principle.

§ 2. Terms

(1) Full blood donor is a person donating full blood.

(2) An apheresis donor is a person donating plasma, thrombocytes or erythrocytes by the method of apheresis.

(3) [Repealed - RT I, 07.03.2011, 1 – entered into force 10.03.2011]

(4) A thrombocyte apheresis donor is a person from whose blood thrombocytes suspended in plasma are extracted.

Chapter 2
CRITERIA FOR DONOR SELECTION

§ 3. Age and body weight of a donor

(1) A donor is a person aged between 18 and 65.

(2) A donor must weigh at least 50 kg.

§ 4. Level of haemoglobin, protein and thrombocytes in donor blood

(1) The haemoglobin level in the blood of a donor must be:
1) for women at least 125 g/l;
2) for men at least 135 g/l;
3) upon donating two doses of erythrocytes by the method of apheresis 140g/l.

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

(2) The level of protein in the blood of a donor of apheresis must be at least 60 g/l.

(3) The number of thrombocytes in the blood of a donor of thrombocyte apheresis must be greater than or equal to 150 × 10⁹ per litre.

§ 5. Diseases excluding blood donation

(1) Blood donation is excluded upon:
1) heart and cardiovascular diseases, except for completely healed congenital deviations;
2) serious disorders of the central nervous system;
3) coagulation disorders;
4) repeated seizures of fainting and cramps, except if the seizures of cramps have taken place in childhood, or if at least three years have passed since the administration of the last medicinal product for cramps and no cramps have occurred thereafter;
5) a serious chronic disease of the gastrointestinal tract, urogenital tract, haematological, immunological, metabolic, renal disease or a disease of the respiratory tract;
6) diabetes, if treated with insulin;
7) malignant tumour, except if cancer at beginning phase (carcinoma in situ) was diagnosed and it has been completely healed.

(2) Blood donation is excluded upon the following communicable diseases:
1) hepatitis B and positive markers of infectious agents of hepatitis B (except for immune HBsAg negative persons);
2) hepatitis C and positive markers of infectious agents of hepatitis C;
3) positive markers of infectious agents of AIDS and H1 virus;
4) positive markers of infectious agents of HTLV I/II and HTLV I/II;
5) babesiasis;
6) Kala-azar (visceral leishmaniasis);
7) Chagas disease.

(3) Donation of blood is excluded in the event of a suspected infection with prion diseases (spongiform encephalopathy – Creutzfeldt-Jakob disease or a variety thereof). Also persons with a history of that disease in the family and recipients of dura mater or corneal grafts, or persons having taken medicinal products originating from human pineal gland may not donate blood.

§ 6. Other factors excluding the donation of blood

Blood donation is excluded upon the following conditions:
1) xenotransplantation of tissue or an organ;
2) sexual behaviour that may place the person wishing to donate blood into heightened risk of becoming infected with communicable diseases carried by blood;
3) using medicinal products not prescribed by doctor administered into veins and muscles, including the use of steroids and hormones aimed at increasing the muscle mass.

§ 7. Diseases limiting blood donation

(1) Blood donation is limited upon:
1) brucellosis – blood donation is not allowed for 2 years after complete healing;
2) osteomyelitis – blood donation is not allowed for 2 years after being declared healthy by a doctor;
3) Q fever – blood donation is not allowed for 2 years after being declared healthy by a doctor;
4) syphilis – blood donation is not allowed for 1 year after being declared healthy by a doctor;
5) toxoplasmosis – blood donation is not allowed for 6 months after complete healing;
6) tuberculosis – blood donation is not allowed for 2 years after being declared healthy by a doctor;
7) rheumatic fever – donation of blood is not allowed for 2 years after the disappearance of the symptoms, except in the event of the occurrence of chronic heart disease symptoms;
8) fever – blood donation is not allowed for 2 weeks after the disappearance of the symptoms;
9) influenza-like disease – blood donation is not allowed for 2 weeks after the disappearance of the symptoms;
10) West Nile Virus (WNV) – donation of blood is not allowed for 28 days from leaving an area where the West Nile Virus is continually spreading to people.

(2) In the event of malaria donation of blood is restricted if the person has:
1) lived in an area of malaria for the first five years of life – donation of blood is not allowed for 3 years after the last visit to an area of malaria, provided that the person has no symptoms of malaria. The prohibition of
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- donating blood may be decreased to 4 months if the immunological or molecular-genetic analysis is negative upon the donation of blood;
- suffered from malaria – donation of blood is not allowed for 3 years after the completion of treatment and disappearance of the symptoms only if the immunological or molecular-genetic analysis is negative;
- been in an area of malaria and the person has no symptoms of malaria – donation of blood is not allowed for 12 months after the departure from the endemic area, except in the event that the immunological or molecular-genetic analysis is negative;

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

- suffered from undiagnosed fever disease during presence in an area of malaria or six months thereafter – donation of blood is not allowed for 3 years after the disappearance of the symptoms. The prohibition of donating blood may be decreased to 4 months if the immunological or molecular-genetic analysis is negative for malaria.

§ 8. Other factors restricting the donation of blood

(1) Donation of blood is restricted for 6 months or 4 months, provided that a test of hepatitis C virus and HI virus carried out by NAT method was negative, after the following procedures and circumstances:
   1) tattooing, perforation of skin and mucous membrane;
   2) acupuncture, unless the treatment was provided by a doctor, using special sterile needles for single use;
   3) transfusion;
   4) endoscopic procedures;
   5) complicated operation;
   6) transplantation of human tissues or cells;
   7) blood splashes on mucous membrane or an injury by a needle contaminated with blood;
   8) contact with a person suffering from hepatitis B.

(1) In the event of a tick bite, donation of blood is allowed after two months from the tick bite, if a person is healthy.

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

(2) For persons whose behaviour or activity exposes them to a risk of being infected with diseases spreading by blood, donation of blood is allowed after the termination of risk behaviour after a period assigned according to the nature of the disease and the results of relevant tests.

(3) During pregnancy and breast feeding donation of blood is prohibited. Donation of blood is allowed after 6 months from giving birth or a miscarriage, except in the event of different instructions of a doctor.

(4) In the event of vaccination, donation of blood is allowed as follows:
   1) with weakened viruses or bacteria – donation of blood is allowed after 4 weeks;
   2) with inactivated viruses, bacteria or Rickettsiae – blood donation is allowed if the person is healthy;
   3) toxins – donation of blood is allowed if the person is healthy;
   4) vaccine of virus hepatitis A – donation of blood is allowed if the person is healthy;

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

- vaccine of rabies – donation of blood is allowed if the person is healthy. If the person was vaccinated as a consequence of biting by an animal with rabies, donation of blood is prohibited for one year;
- vaccine of tick encephalitis – blood donation is allowed if the person is healthy.

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

- Vaccine of virus hepatitis B – blood donation is allowed after one week if the person is healthy.

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]

(5) In the event of using medicinal products the donation of blood is restricted pursuant to the effect of the medicinal product and the disease treated therewith.

(6) In the event of a small operation donation of blood is allowed in one week.

(7) In the event of dental treatment donation of blood is allowed on the following day.

(8) Due to an epidemiological situation the donation of blood is restricted according to the instructions of the Health Board.

[RTL 2009, 99, 1482 – entered into force 01.01.2010]

(9) Donation of blood may be prohibited if a mental or behavioural disorder has been detected in a person, or if the age of a donor donating blood for the first time is over 60 years and the state of health is unsuitable for blood donation according to the evaluation of a doctor.

[RT I, 07.03.2011, 1 – entered into force 10.03.2011]
§ 9. Exceptional selection of a donor

As an exception, a doctor may give permission to donate blood to a donor not corresponding to the requirements provided in paragraphs 3 and 4. Such exceptions must be documented in writing, including the reasons for exception.

Chapter 3
TERMS AND PROCEDURE FOR DONOR SELECTION

§ 10. Donor selection

1) The purpose of donor selection is to protect the recipient from the adverse effects of diseases and medicinal products communicated by blood and not to harm the health of a donor donating blood.

2) Donor selection is performed by a doctor or a nurse having passed a relevant training (hereinafter doctor) under the supervision of a responsible doctor.

§ 11. Donor questionnaire

1) A donor fills a questionnaire with the purpose to describe his/her state of health and lifestyle.

2) The questionnaire includes questions:
   1) regarding the state of health, treatment procedures undergone, medicinal products administered and illnesses;
   2) regarding trips abroad;
   3) regarding habits of behaviour.

3) A donor questionnaire is signed by a doctor and the donor.

§ 12. Operations of a doctor in selection of a donor

1) Upon the selection of a donor, a doctor performs the following:
   1) conduct a personal discussion with the donor in conditions ensuring confidentiality with a purpose to obtain an overview of the state of health of the donor, illnesses in the past and possible risk behaviours;
   2) evaluate the general state of the donor;
   3) measure the physiological parameters of the donor.

2) Within the evaluation of the general state of the donor, the doctor inspects the following characteristics of the donor:
   1) mental state;
   2) physique and body weight;
   3) swelling in face and limbs;
   4) disturbance of breathing;
   5) colour of skin and mucous membranes;
   6) state of skin;
   7) state of the lymph nodes;
   8) suitability of veins for drawing blood.

3) Upon the selection of a full blood donor, the doctor measures the following:
   1) level of haemoglobin (hereinafter Hb) or hematokrit (hereinafter Hct) in the blood of the donor upon every donation of blood;
   2) pulse and blood pressure of a donor donating blood for the first time and thereafter upon every blood donation if the donor is older than 45, has body weight under 55 kg or is overweight (body mass index over 25), has complaints about any health situation or if the donor has had a deviation from the norm of blood pressure or pulse during a prior medical examination.
   [RT I, 07.03.2011, 1 – entered into force 10.03.2011]

4) Upon the selection of a donor of apheresis, the doctor measures the following:
   1) level of Hb or Hct upon every blood donation;
   2) pulse and blood pressure upon every blood donation;
   3) total protein at least once a year;
   4) clinical blood analysis once a year.
   [RT I, 07.03.2011, 1 – entered into force 10.03.2011]

5) In the event of a selection of a donor for thrombocyte apheresis, a doctor shall examine also the number of thrombocytes in blood upon every donation of blood, in addition to figures provided in section 4.
   [RT I, 07.03.2011, 1 – entered into force 10.03.2011]
(6) Based on the information obtained in personal discussion and evaluation of the general state and measurement of the physiological parameters of a person, the doctor decides if the person can donate blood or not.